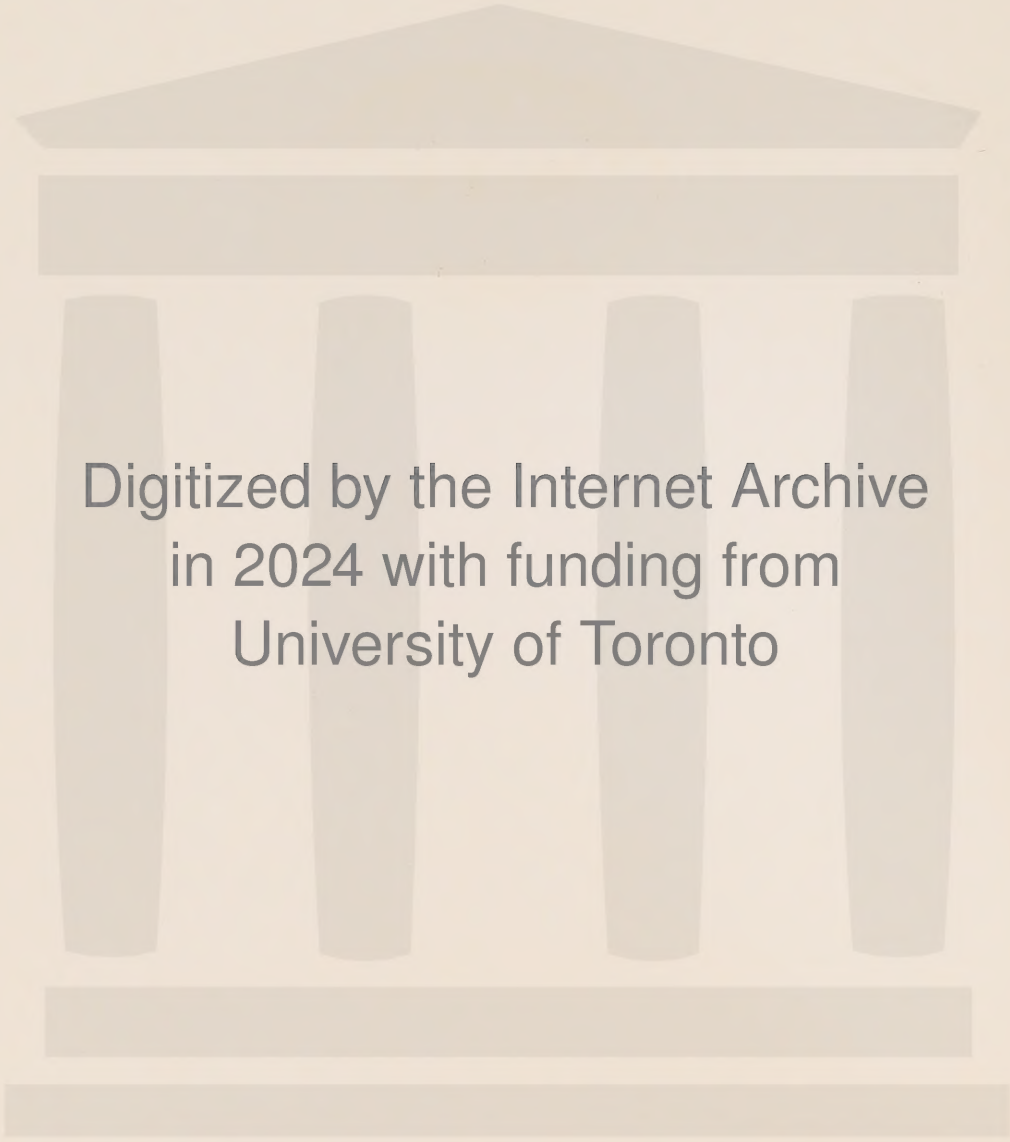
REPORT OF THE OMBUDSMAN'S OPINION, REASONS THEREFOR, AND RECOMMENDATIONS FOLLOWING HER INVESTIGATION INTO THE COMPLAINT OF MS. W.

SEPTEMBER, 1989



The Ombudsman | Ontario
L'Ombudsman | Ontario

Eleanor Meslin, LL.B.
Temporary Ombudsman
Ombudsman intérimaire

125 Queen's Park
Toronto, Ontario
M5S 2C7
(416) 586-3300

September 12, 1989

The Speaker
Legislative Assembly
Province of Ontario
Queen's Park
Toronto, Ontario

Dear Mr. Speaker:

On this occasion, I wish to present a Special Report containing the results of my investigation into the complaint of Ms. W. This report is submitted pursuant to section 22(4) of the Ombudsman Act.

As you will see, the Ministry of Health has declined to implement my recommendations in this case.

As you are aware, such cases are usually reported at the same time each year in my Annual Report. However, when in my opinion special circumstances or urgency exist, I do not wait for the issuing of my Annual Report; I submit a report, such as this, to speed-up the process and hopefully obtain a resolution of the complaints, through the Standing Committee.

The Standing Committee on the Ombudsman is prepared to consider cases reported in this manner on a priority basis.

In my opinion, such expeditious consideration of complaints serves the interests of both the complainants and the governmental agencies involved.

Yours sincerely,

E. Meslin

Eleanor Meslin

Attachment

REPORT OF THE OMBUDSMAN'S OPINION,

REASONS THEREFOR, AND RECOMMENDATIONS

FOLLOWING HER INVESTIGATION INTO THE COMPLAINT OF

MS. W

Ms. W registered her complaints against the Ministry of Health in July 1987. She contended that the Ontario Health Insurance Plan's refusal to reimburse her for the cost of renting an electric breast pump to feed her infant son who was born prematurely was unreasonable.

On July 13, 1987 the then Deputy Minister of Health, Dr. Allan E. Dyer, was advised of the Ombudsman's intention to investigate Ms. W's complaint. At the same time Dr. Dyer was invited to provide this Office with statements of his organization's position with respect thereto.

Dr. Dyer responded in a letter dated August 28, 1987 in which he referred to Regulation 452 under the Health Insurance Act which listed specified health services covered by the Ontario Health Insurance Plan. He said that under the Regulation, the Ontario Health Insurance Plan was designed to cover such health services and that "the Plan currently covers medically necessary services rendered by physicians, and dental procedures in the hospital"; Dr. Dyer went on to state "special appliances are specifically excluded as an insured benefit of OHIP in Section 53(1) 9 of Regulation 452." The response also advised us that the Minister's Advisory Committee on Assistive Devices had addressed the issue of covering breast pumps under the Assistive Devices Program and "... gave it low priority among devices to be added for coverage in the future."

In the course of our investigation we conducted interviews with the following: the Director of the Assistive Devices Branch; Dr. A, Chairman of Advisory Committee on Assistive Devices; Mr. Malcolm Gibson, the then Manager of the Ontario Health Insurance Plan and three doctors, members of the Professional Services Branch, Ministry of Health. We also held a number of discussions with Dr. Martin Barkin, Deputy Minister of Health and five members of his staff. In addition we spoke with Dr. D, Head of the Breast Feeding Clinic at an Ontario children's hospital; and the Assistant Director of Social Workers at the hospital where the baby was born.

As part of our investigation we reviewed submissions by Ms. C, Senior Clinical Dietician-Nutritionist, at a children's hospital, and Dr. B, Chief, Division of Neonatology, at the hospital where the baby was born.

This Office also carried out its own literature research which included studies done in Sweden, the United States and India.

After a careful review of the documented evidence as well as oral evidence presented to me and members of my staff by the parties involved, I came to certain tentative conclusions and tentative

recommendations. Accordingly, I wrote to the Deputy Minister of Health on March 9, 1989 in accordance with Section 19(3) of the Ombudsman Act and invited him to make representation with respect to the following:

Possible Conclusions

1. The decision by the Ministry of Health to refuse to cover the cost of renting electric breast pumps for feeding premature infants in hospitals with their mother's milk was unreasonable.

2. The Ministry's decision to exclude breast pumps from coverage in Section 53 (1) 9 of Regulation 452 under the Health Insurance Act was unreasonable.

3. The Ministry's omission to provide an adequate process through which to consider electric breast pumps under the Assistive Devices Programme was unreasonable.

4. The act by which the Ministry's decisions with respect to priorities are made in the Assistive Devices Programme is in accordance with a practice which is unreasonable.

[Reference: Ombudsman Act, section 22(1)(b)]

Possible Recommendations

1. The Ministry of Health should further consider including, as an insured service, the cost of electric breast pumps specifically for feeding premature infants, by amending its criteria for defining "special appliances" in Regulation 452 Section 53(1) 9 under the Health Insurance Act, such that breast pumps are excluded from this category, and included under Section 39 of Regulation 452, specifically for premature babies when prescribed by a physician or the medical staff of a hospital. [Reference: Ombudsman Act, section 22(3)(e)]

2. The Ministry of Health should also develop clear criteria for managing the Assistive Devices Programme. [Reference: Ombudsman Act, section 22(3)(b)]

I based these tentative conclusions and recommendations on the following information:

Ms. W's first baby was born prematurely. Her subsequent three pregnancies, in keeping with medical probability, also resulted in babies born prematurely, including twins who did not survive. A daughter born at 34 weeks remained in hospital for 7 weeks, during which Ms. W rented an electric breast pump. Ms. W's last child was born on March 17, 1987 in an Ontario hospital at 25 weeks' gestation. While in hospital she used the one electrical breast pump attached to a special care unit. There was usually a line up for use of the pump. Acting upon the advice of her physician, Ms. W rented an Egnell-Ameda Breast Pump from March 21, 1987 when she left hospital. She had tried hand expressing with the aid of two

different types of manual pumps. These methods were found to be useful for the collection of an occasional bottle but were not sufficient in providing the stimulation required to produce enough volume to meet the complete daily nutritional needs of a baby. The cost of renting the pump was $363.78.

Dr. B, Chief, Division of Neonatology at an Ontario hospital, confirmed that baby W was born in that hospital on March 17, 1987 at 25 weeks' gestation. He also confirmed that Ms. W was encouraged to breast feed her baby. Dr. B stated that "it is the policy of most Neonatal units to actively encourage mothers of premature babies to provide breast milk because of the universally-recognized physiological benefits to the infants and the psychological advantages to both them and their mothers."

Ms. C, Senior Clinical Dietician-Nutritionist at an Ontario children's hospital, stated "most Neonatal Intensive Care units work very hard to promote the use of Mother's Own Milk for her infant." Ms. C pointed out that because for days or weeks an infant may be too tiny, weak or otherwise unable to suckle at the breast, it is essential that mothers use a mechanical pump to produce the needed milk. She confirmed that hand and battery operated pumps are only adequate for occasional pumping for mothers well-established in breastfeeding their infants. Ms. C viewed the electric breast pump as the only solution for the mothers of this special group of children in Neonatal Intensive Care Units. As a Dietician-Nutritionist, Ms. C felt "very strongly that this kind of equipment is as vital as a feeding pump is to the enterally or parenterally fed patients" (hyperalimentation is covered under Regulation 452, section 39 7).

Nutrition services such as that of the local Health Department consistently advise mothers through publications that breast milk contains important anti-infective agents that help protect babies from germs. Mothers are also advised that if allergies run in their family, exclusive breastfeeding will protect babies during the early months. From this we might reasonably conclude that such protection would be even more vital to the very vulnerable premature infant.

In the course of our investigation my staff first attempted to determine the general process by which devices are added to the Assistive Devices Programme, and in particular the rationale for the ranking of breast pumps as a low priority.

My investigative staff made several unsuccessful attempts to obtain from the Assistive Devices Branch documentation which would reflect how the process works in general, as well as the Advisory Committee's deliberations, reporting and recommendations to the Ministry on this particular issue. We were advised that the Branch would attempt to obtain the information from the Minister's Advisory Committee on Assistive Devices. In the meantime, on May 5, 1988 three members of my staff attended at the Ministry and held a meeting with the Director of the Assistive Devices Branch. Their discussion included a review of the Programme's history and revealed that the Assistive Devices Programme was established to develop a service for children under the age of 18 with long-term physical disabilities. It is my understanding that the Ministry felt that in order for such children to progress they should be assisted with special devices, which often needed to be changed as they grew.

Following extensive advocacy by organizations of and for the disabled, the age restriction was eliminated recently and the list of devices expanded. The Ministry relies on information and guidance from the Advisory Committee, but submits the actual items for consideration by the Committee. There does not appear to be any set criteria or guidelines for deciding what items should be added to the Programme. My staff also determined that the Assistive Devices Branch does not have a formalized process for data collection, nor a structured means of conducting assessments of consumer needs. Currently there is an intake process, but no means of retaining statistical information on inquiries or requests for coverage. We were advised that there are plans for a computerized system of data collection, but it is anticipated that the system will not have the capacity to retrieve and store statistical information on requests for assistive devices which are not currently on the list.

We were referred by the Ministry to the current Chairman of the Advisory Committee, Dr. A, to obtain documentation on the Committee's deliberations on this issue. He advised my staff that the minutes of the relevant meeting were in the possession of the Director of the Assistive Devices Branch by whom my staff had just been referred. Dr. A agreed to request them, but explained that although the meeting in question took place before his time with the Committee, he was of the opinion that the minutes would not reflect discussion on coverage of breast pumps. It was his understanding that the matter was dealt with perfunctorily as it was not considered "relevant" to the Committee at that time.

On August 23, 1988 we received a written response from Dr. A, concerning our request for the documentation. He advised us that in late 1986 a list was developed by the program staff, Assistive Devices Branch, on behalf of the Committee. Breast pumps were included on the list, considered at a meeting on January 20, 1987 and subsequently reviewed at a meeting on March 25, 1988. However, the minutes of both meetings did not specifically make reference to any discussion concerning breast pumps. Dr. A provided us with copies of the minutes, and, in the absence of any record of the rationale for not adding electric breast pumps to the list, offered his own opinion which included such considerations as:

- **Demand** - requests to Assistive Devices Programme for inclusion have been few.

- **Need** - numbers of women requiring powered pumps are few.

- **Availability** - neonatal units of hospitals or La Leche League loan powered pumps.

- **Fit with the mandate of the program** - the program provides some rehabilitative devices and supplies which are required as a result of a chronic disability or condition. It is anticipated that the devices would be required for an extended period, usually greater than 6 months. While breast pumps could be included given this, the rehabilitative nature of the device is tenuous, as is the frequency of need for periods longer than six months. Accordingly, provision of pumps might better fit within the mandate of local neonatal units at the hospitals.

Dr. A concluded that, given the above considerations, he did not think the device would rank as a recommended priority. However, he would be willing to have the Committee review its recommendation to the Minister of Health if this Office indicated that such a review was warranted, considering the above.

Following this correspondence my staff met with Dr. A on September 23, 1988, at which time the various points raised were discussed in depth. Dr. A expressed the Committee's eagerness to receive input from various sections of the community, including this Office.

During discussions with the Professional Services Branch of the Ministry, my investigator was advised that, apart from the Assistive Devices Programme, there is no record of consideration for coverage of breast pumps. She further determined that in Regulation 452 s. 53(1) 9, the "special appliance" label (by which breast pumps were identified in the Ministry's response) refers to devices which are not implanted in the body. She was told that the Ministry's policy is that any device implanted in the body in hospital is covered, any other device is not. My investigator noted that under s. 39 6 and 7 there is extended coverage for renal dialysis equipment, supplies and medications as well as hyper-alimentation equipment, supplies, and medications as insured out-patient services. Since these are not implanted devices, my investigator inquired further, on the basis that they appeared to be exceptions to a general rule. The Ministry appeared to accept their status as "exceptions" but pointed out that it was a political decision to include these items as insured services, a decision which reflected the need to get people out of hospital beds. However, the groups to whom the exceptions apply are easily identified - they have life-threatening diseases, and are in need of continuous service. Ministry officials stressed that premature infants do not fit these categories. In my opinion this is arguable, since many premature infants arrive in the world in highly life-threatening circumstances.

Our own literature research suggested that, for this special group of infants, there are several advantages to the use of human milk. While it was acknowledged that human milk fortification may be necessary to optimize nutritional support, the anti-infective properties appeared to be unquestioned. I determined that the ability of breast milk to confer passive immunity has withstood the test of time and remains the impetus to encourage breast milk feeding. Since human milk contains many components which may both promote a normal bacterial colonization of the gastro-intestinal tract and also suppress the invasiveness of certain pathogenic micro organisms, the qualities attributable to breast milk appear to be of major importance for the newborn infant's defence against infection.

For example, research suggests that the highly lethal acute necrotizing enterocolitis is predominantly a disease of the relatively immune-deficient premature infant, and that breast milk may protect these at-risk premature infants from acute enterocolitis. Several other studies provide ample evidence for the presence of anti-infection factors in human milk, and support its use especially for premature infants.

The growth in knowledge about neonatal medicine, accompanied by an increase in the technical means to both treat neonatal diseases and

monitor therapies, has resulted in the survival of large numbers of very, very low weight infants. These advances appear to be generating new challenges for nutritionists. The very, very low birth-weight infants' limited nutritional reserves, high requirements for normal growth and development, as well as their gastrointestinal immaturity, appears to pose a particularly challenging nutritional problem. However, given the potential consequences of inadequate or inappropriate nutritional management, it seemed to me that the obligation of health professionals was to make nutrition a high priority in the over-all care of very, very low birth-weight infants. While the importance of various fortifiers was accepted, my understanding was that researchers clearly demonstrated a preference for milk from the infant's mother. This led me to the view that it remains reasonable that the majority of premature infants are best served by encouraging the mothers to supply breast milk for their early feedings, and by promoting successful transition to feedings at the breast as they mature.

Under current legislation, insured hospital services include accommodation and meals, all medical needs as determined by a physician and medical services rendered by physicians (Regulation 452, s. 38). The Regulation makes no distinction where feeding (meals) is achieved with the aid of devices or appliances such as I.V. units, feeding tubes, feeding pumps, etc. It appeared to me that the intent of the legislation was to provide quality medical care for patients in hospital. The hospital's global budget provides coverage for whatever is medically desirable to put right the patient's condition and it was my view that it is the right of patients to expect the best available long-term medical option - not merely short-term solutions. I felt that it was reasonable to assume that an important, indeed a basic, consideration in health care is providing the most appropriate form of nourishment to the patient. I pointed out that under s. 38 of Regulation 452 neither the appliances used nor the related preparations for feeding which are prescribed by an attending physician "... in accordance with accepted practice and sound teaching and administered in a hospital ..." are excluded from coverage.

In the case of Baby W, the physician determined that his mother's milk should be the primary form of nourishment and specifically advised his mother to provide her own milk. The suitability of prescribed feeding for the patient was not disputed by the Ministry. It appeared to be in accordance with acceptable medical practice. But the effect of the Ministry's actions was to reserve the right to countermand the recommendation of the physician, by refusing to pay for the rental of equipment which was determined to be necessary, to ensure that the best interest of the infant was met. At the same time, by paying for artificial formulas the effect was that the Ministry wrested from the physician the responsibility to determine what was best for the patient.

In doing so, the Ministry relied on s. 53 of Regulation 452 under the Health Insurance Act which excludes a number of services from insurance under the Plan. The Ministry implied that the breast pump was a "special appliance" for the purposes of s. 53(9) and, thus, was specifically excluded as an insured benefit under OHIP. "Special appliances" were defined by the Ministry as appliances outside the body such as glasses, canes, etc. Thus, since the breast pump does not actually enter the body of the patient-baby, it was deemed to be a

non-insurable "special appliance". This appeared to be a narrow interpretation of the Regulation, which denied premature infants the right to medically necessary services. I also suggested that a mechanism does exist for covering the cost of mechanical aids which ensure the medically desirable nourishment to specific categories of patients, in and out of hospitals.

I pointed out to the Ministry that feeding a patient in hospital is a medically necessary service to which a cost factor is applied; however, it appeared to me that the system's practice, in some cases, was incongruent with its policy. It is the practice of physicians and other health professionals to advise mothers of premature babies to breastfeed their babies, but the policy of the hospitals is to provide formula for the feeding of these infants. In essence, hospitals provide the formula at no additional charge to the patient, while relegating breast milk to the ability of the parents to afford the means of obtaining it. This appeared to be an unreasonable application of the legislation. Furthermore, I felt that any regulation which would result in the denial of a mother's opportunity to breastfeed her baby, premature or full-term, would seem to be unjust. Statements by the Assistive Devices Programme related to low demand actually seemed to argue in favour of the complaint, since, if demand is low, coverage could hardly be viewed as a drain on the health budget. At the same time, it appeared to be unreasonable to deny a necessary medical service to those few who needed it, on the basis that not enough consumers demand it.

On May 2, 1989 there followed discussions with the Deputy Minister and members of his staff during which we were advised that the Ministry of Health does not cover all things which are "good for health". In general the Ministry covers insured services according to the definition in the Canada Health Act and provincial Statutes. The government may then decide to provide other services as a public policy initiative - such as items under the Assistive Devices Program.

In response to questions regarding the decision-making process by which devices are added to the Assistive Devices Programme list, Dr. Barkin, the Deputy Minister of Health, stressed that the process was complex. The Ministry looks at the extent of the disadvantage caused by the refusal to fund. However it was pointed out that the matter was a Cabinet decision within the legislative framework. Dr. Barkin noted that previously there were no guidelines for decision making of this sort but that the Premier had directed his Council on Health to provide some. It is my understanding that a process has now been set in place for determining criteria for making priority decisions. Nevertheless, it was also stressed that objective standards are difficult to provide.

Where there are limited resources, all allocative decisions require those persons supporting one plan to be opposed to those supporting another. The government is subject to a lobbying process and advocates present their case as best they can. The information they provide forms part of the decision-making process. Application of the objectives suggested by the Premier's Council may determine their feasibility in the process. However, it is sometimes not possible to know how a Cabinet decision is made. Again, large population studies may show that a particular program is the best way to spend health dollars; even in

such circumstances, however, the program may not be one which is capable of implementation.

Dr. Barkin also advised us that the Assistive Devices Branch is an operational branch only and does not serve an advisory function. However, I was not satisfied that this statement addressed the concerns which we raised about the Programme. Furthermore, since our discussions with Dr. Barkin, we learned that a major review of the Programme's operation is being undertaken. It would appear that some of the items being examined relate directly to our review of this complaint. Nevertheless, despite our efforts to communicate with the Ministry on this issue, we have been unable to determine the exact nature of that review.

In response to my correspondence setting out my views and opinions as stated above, and outlining my tentative conclusions and recommendations, I received a letter dated June 1, 1989 from Dr. Barkin, in which he referred to our discussion and follow-up notes on the case as well as to my letter of March 9, 1989.

Dr. Barkin reiterated that the Canada Health Act 1984 provides the Programme criteria and conditions of payment for the cash portion of the federal contributions made to the provinces for insured services. He pointed out that the Ontario Health Insurance Plan fully satisfies the comprehensiveness criterion of the Act for insured health services. Dr. Barkin also pointed out that the Assistive Devices Programme was a discretionary service by the province, which was not required to be universal or comprehensive. He further referred to the complexities of the process of adding coverage as was summarized by this Office, arising from our understanding of statements made by Dr. Barkin and his staff.

Dr. Barkin also pointed out that hospitals operate as individual entities whose policies are the mandate of their boards and corporate management groups. He went on to state that Ms. W did not avail herself of the hospital's complaint protocol which is used for investigation of identified problems by patients and families. It was Dr. Barkin's opinion that if the hospital had been advised of the problem, the social work team could have investigated sources of funding to assist her.

On this issue my investigation revealed that social workers at the hospital are employed for counselling and directing patients. They administer a small petty cash fund for such items as bus fare and meals, but essentially connect patients with other needs to agencies such as the Municipal Department of Social Services. Most of the patients thus referred are indigent individuals whose financial needs are easily determined. The service does not apply to everybody and a means test is applied, and only families on marginal incomes are assisted. While breast pumps meet the criteria of services provided by the social work team, we were assured that only the indigent would receive assistance in this area. My investigation ascertained that Ms. W was not an indigent person, and would not have qualified for referral to the Department of Social Services.

Notwithstanding our discussions with the Ministry staff, I am not satisfied that the Ministry's response to my tentative conclusions and recommendations has adequately addressed the issues which I brought to its attention in this investigation.

I have therefore decided to finalize my tentative conclusion that:

1. The decision by the Ministry of Health to refuse to cover the cost of renting electric breast pumps for feeding premature infants in hospitals with their mother's milk was unreasonable.

2. The Ministry of Health's decision to exclude breast pumps from coverage in Section 53(1) 9 of Regulation 452 under the Health Insurance Act was unreasonable.

3. The Ministry of Health's omission to provide an adequate process through which to consider electric breast pumps under the Assistive Devices Programme was unreasonable.

4. The act by which the Ministry of Health's decisions with respect to priorities are made in the Assistive Devices Programme is in accordance with a practice which is unreasonable.

[Reference: Ombudsman Act, section 22(1)(b)]

I have also decided to finalize my tentative recommendations that:

1. The Ministry of Health should further consider including, as an insured service, the cost of electric breast pumps specifically for feeding premature infants, by amending its criteria for defining "special appliances" in Section 53(1) 9 of Regulation 452 under the Health Insurance Act, such that breast pumps are excluded from this category, and included under Section 39 of Regulation 452, specifically for premature babies when prescribed by a physician or the medical staff of a hospital. [Reference: Ombudsman Act, section 22(3)(e)]

2. The Ministry of Health should also develop clear criteria for managing the Assistive Devices Programme. [Reference: Ombudsman Act, section 22(3)(b)]

This report was sent to the Minister of Health on August 29, 1989. I invited the Ministry to respond to my recommendations at any time prior to meeting with the Standing Committee on the Ombudsman. As of publication of this special report, no response has been received.